

User Manual



CASS Regulator:

Model 3720



**Boehringer Laboratories, LLC
300 Thoms Dr.**

**Phoenixville, PA 19460
800-642-4945**

Covered under one or more of the following patents:
6,264,890 6,228,056
5,992,239 5,879,624 5,409,491
5,372,593 5,354,262 5,203,778

Other Patents Pending
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WELCOME

Congratulations on your purchase of a Boehringer Suction Regulator. We consider our Suction Regulators to be the best in the world. We are confident they will provide you with reliable, trouble-free, safe patient care and low cost of operation. This product is intended for use by individuals properly trained in suctioning procedures by or on the order of a physician. Please read these instructions carefully.

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Definition of Terms and Symbology

VACUUM	Air or other gases at a sub atmospheric pressure typically expressed as mmHg or cmH ₂ O.
SUCTION	A use of vacuum that causes a fluid or solid to be drawn into an interior space or to adhere to a surface because of the difference between the external and internal pressures.
	Alerts the user to the presence important operating and maintenance instructions in the literature accompanying the device.
WARNING	Alerts user to actions or conditions that could result in injury to user or patient.
CAUTION	Alerts user to actions or conditions that can cause damage to the device <u>or</u> may result in substandard performance of the device or system.
IMPORTANT	Indicates an action that is emphasized to ensure proper operation of equipment.
OFF	Supply suction is off and patient circuit is vented to atmospheric pressure.
REG	Supply suction is on and regulated output is controlled to prescribed setting.
LINE	Supply suction is on and regulation is bypassed to deliver maximum suction to collection circuit.
CONTIN	Intermitting regulator setting that provides continuous regulated suction to the collection circuit.
INT	Intermitting regulator setting that allows periodic, automatic application & venting of the collection circuit.
	<p>Lo Spike: Accuracy of regulation depends primarily on the ability to provide a consistent level of vacuum under changing flow conditions.</p> <p>Involuntary pneumatic biopsy, or tissue damage, can occur when high levels of vacuum are applied to delicate tissue. With a Boehringer regulator, you can depend on very low "spike" compared to our competitor's models.</p> <p>"Spike" is the variation in indicated suction as flow in the collection circuit changes from an a free flowing condition to an occluded condition. We measure spike as the change in indicated suction from full flow to a no flow condition using a typical collection circuit with a 14 French catheter. To test, set the regulator to 100 mm flowing, and then allow occlude the 14Fr catheter. The change in the indicated suction level is "Spike".</p> <p>Boehringer regulators are checked on the assembly line to meet a specification of less than 10% of the indicated setting, for example 10mmHg spike at a 100 mmHg setting.</p> <p>An evaluation of a regulator's spike allows one to determine whether the device is truly "regulating". A safe and reliable regulator should regulate to its set position regardless of variable flow conditions.</p>
PARALLAX	Inaccuracy caused by observational position of an indicating element (pointer) to a reference element (scale).

SAFETY INFORMATION

WARNING

- This product is intended for use by or on the order of a physician. It is to be used by individuals who are properly trained in medical suctioning procedures. Please read these instructions carefully.
- The Boehringer CASS regulator should not be used for closed wound drainage, pleural suctioning, thoracic drainage, or any application that does not afford an atmospheric vent for the suction circuit. The CASS button provides a momentarily high suction pulse which could cause localized barotrauma if not allowed to quickly vent the suction back to atmosphere.
- Suction regulators must only be attached to vacuum systems. Do not attach to compressed air, nitrogen, or oxygen sources.
- Suction catheters, collection canisters and suction tubing must be carefully evaluated and selected to ensure adequate function for the specific clinical environment and intended field of use.
- Do not use Boehringer suction regulators in the presence of flammable anesthetics.
- There have been reports of increased intracranial pressures associated with endotracheal suctioning procedures. "Persistent, increased ICP has been associated with neurological damage and fatalities". (ECRI, Healthcare Product Comparison System (US). Regulators, Suction. Plymouth Meeting (PA), 1999.).

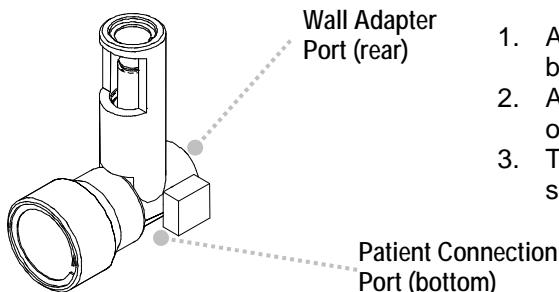
CAUTION

- Collection canisters are mandatory for all suction procedures. We strongly recommend the use of an overflow protection device (filter or trap bottle) at all times between the regulator and collection canister. See Accessories at the end of this manual.
-  Always verify regulator operation (LoSpike, see page 4 for details) before use on a patient. Verify operation by establishing the desired vacuum level with the collection circuit and suction catheter attached to the regulator. Occlude the suction catheter and note that the indicated vacuum does not rise by more than 10% of the original setting.
- Intermittent Regulators: The automatic return of the patient circuit to atmosphere may not eliminate the need for catheter tip irrigation. As with any automatic system, it is important to monitor the results to be sure that drainage is occurring in a safe efficient manner. The fact that the intermitter is cycling is not an indication that effective drainage is occurring.
- The Model 3708 Boehringer MRI Suction Regulator is the only MR conditional regulator with FDA 510K approval.

INSTALLATION

All Boehringer suction regulators are supplied with 1/8" NPT female ports. The standard port facilitates simple adaptation to any quick disconnect system. Fittings are available from Boehringer to adapt to your quick connect system. We recommend you purchase the appropriate fittings with your regulator at the time of purchase. The fittings will then be factory installed prior to shipping. By purchasing the regulator and fittings (a complete system) simultaneously, the factory will apply the unmatched 10 Year Warranty of our suction regulators to the fittings as well. See 14 for complete warranty details.

In the event that you must assemble or disassemble fittings, please follow these instructions:

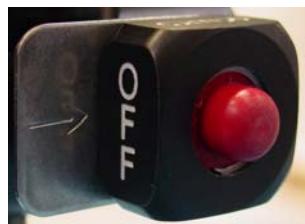
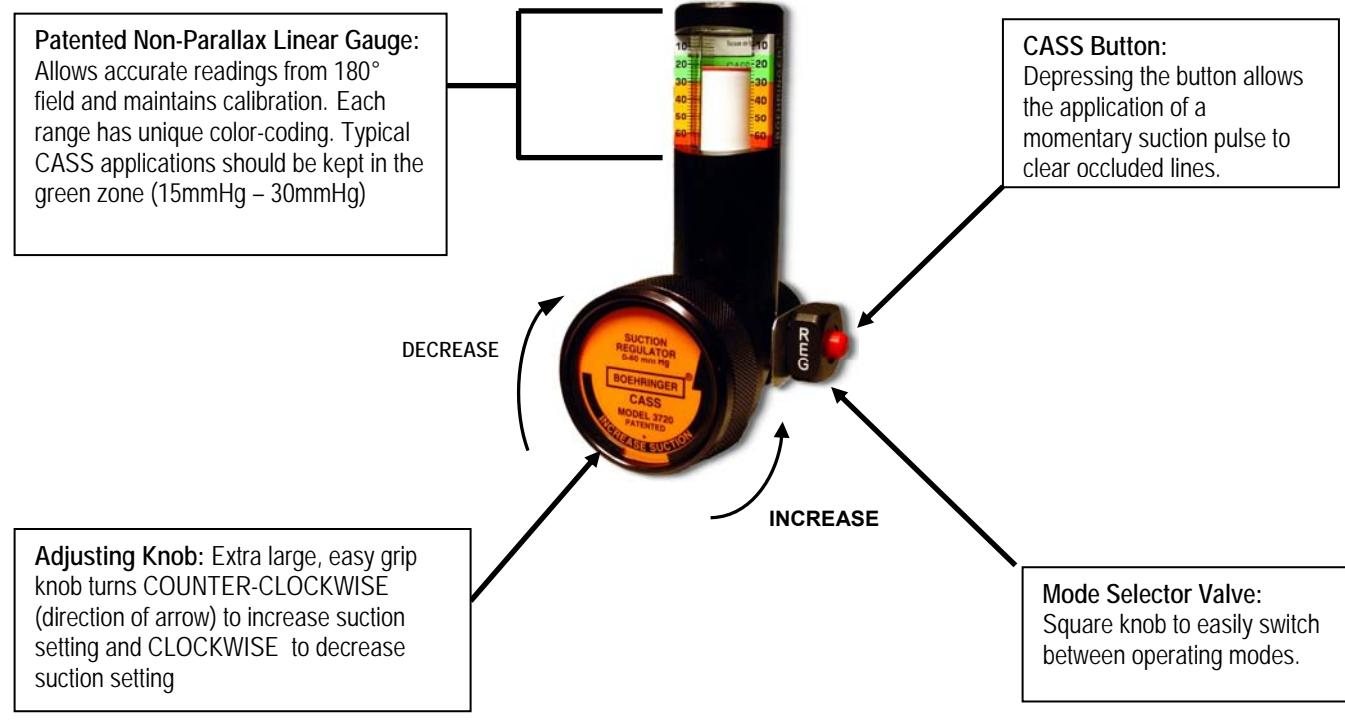


1. Assemble desired male quick connect to the wall adapter port on the back of the regulator using thread sealant.
2. Assemble the desired inlet fitting to the patient connection port bottom of the regulator using Teflon tape or thread sealant.
3. The regulator is now ready to be placed in service on your suction system.

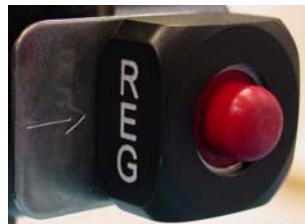
Location	Configuration requirement	Order Number and Description	
Patient Connection Port	Suction tubing attached directly to the suction regulator	Model 2469 High Flow Bubble Barb	
	Suction regulator attached to collection canister, rollstand or trap bottle	Model 1487 DISS Body Adapter	
Wall Adapter Port		Model 1492 Diamond Ohio	
		Model 1493 Chemetron (NCG) Rectangular Adapter	
		Model 1504 DISS Hand-Tight Nut and Gland	

For special adapter requirements, please contact us at 800-642-4945.

FEATURES & OPERATION



Selector Valve OFF:
The regulator and CASS feature are turned off.



Selector Valve REG:
The regulator is on and suction can be adjusted via the adjusting knob. The CASS feature may be activated by depressing the CASS button.

CLINICAL USE

The CASS regulator has been specifically designed to function in conjunction with artificial airways designed to remove subglottic secretions (Mallinkrodt Hi-Lo Evac®; Smiths Medical Suctionaid®, Teleflex ISIS™ HVT™).

With the low levels of suction prescribed for CASS, aspiration lines may become clogged with biological fluids. To combat blockages, the Boehringer CASS regulator incorporates a second regulating circuit. This second circuit allows a momentary suction pulse, similar to that generated with a syringe, which allows the user to clear the occluded lines without the use of a syringe or the need to open the patient circuit. This suction pulse is provided independent of the main regulated setting.

The suction pulse can only be applied when the red CASS button is depressed. The suction pulse is regulated and flow restricted. It will have no impact on a free flowing suction circuit.

Continuous Aspiration of Subglottic Secretions (CASS) is typically performed with a suction setting in the range of 15-30mmHg. This range is indicated by a green colored zone on the regulator gauge. An appropriately sized collection canister must be used in between the regulator and the patient. Before connecting the collection circuit to the patient, ensure suction is present when the regulator is on. This can be felt with a gloved hand over the open attachment of the collection circuit closest to the patient. (See "Safety Information").

If the suction line is suspected of being blocked, the CASS button can be depressed until there is visible movement of secretions in the suction line. At no time should the CASS button be depressed for more than 30 seconds continuously.

CAUTION

The regulator must be serviced if at any time the CASS button fails to return to its original position, material is sucked into the regulator when the CASS button is depressed, or if the regulator cannot maintain a clinically safe suction setting.

The following articles may be referenced for more detailed clinical information - -

- Valles J, Artigas A, Rello J, Bonsoms N, Fontanals D, Blanch L, et al. Continuous aspiration of subglottic secretions in preventing ventilator-associated pneumonia. *Ann Intern Med* 1995;122:179-186.
- Mahul P, Auboyer C, Jospe R, Ros A, Guerin C, el Khouri Z, et al. Prevention of nosocomial pneumonia in intubated patients: respective role of mechanical subglottic secretions drainage and stress ulcer prophylaxis. *Intensive Care Med* 1992;18:20-25.
- Kollef MH, Skubas NJ, Sundt TM. A randomized clinical trial of continuous aspiration of subglottic secretions in cardiac surgery patients. *Chest* 1999;116:1339-1346.

MAINTENANCE

Your Boehringer Regulators have been designed to provide years of trouble free operation. Most service activity is the result of aspiration of bodily fluids into the regulator. The routine use of an appropriate collection canister greatly reduces needed service. To determine your cleaning/maintenance schedule:

- Periodically inspect the overall condition of the instrument. Test the gauge accuracy and check the instrument function as described under 'Test'. Simply clearing the small orifices in the gauge view tube and the regulator body can remedy many performance conditions (see troubleshooting). Return to service if the instrument performs appropriately per the 'Test' requirements. It is especially important on the CASS regulator to ensure the regulator orifice, found opposite the control valve, is free of lint and other debris. The orifice is approximately 0.3mm. A 29 gauge needle or #80 drill or smaller tool may be used to clear any accumulated lint from this entry. If the orifice of your regulator has a stainless steel filter, this can be cleaned by wiping the outside of the filter with a lint free cloth.



- Based on data from your periodic inspections, determine a cleaning/maintenance schedule appropriate for the operational conditions of your facility. Clean, inspect, lubricate, and test based on your schedule and according to the Instrument Cleaning and Disinfection, Instrument Lubrication and 'Test' section outlined below.

TEST

1. With the control valve in the REG or CONTIN position and a collection system attached with a 14 Fr. catheter, regulator should control vacuum from 10-100% of full scale (FS).
2. With the control valve in the REG position and housing turned all the way off, with suction port occluded, gauge should read zero.
3. With the control valve in the REG position, adjust regulator to the middle of the scale and occlude the catheter. Gauge movement should be less than 5% of the full scale of the regulator. This measurement is called droop.
4. The gauge should be accurate to $\pm 5\%$ FS for any measurement within the range of the scale. If this is not the case, please return the gauge to the manufacturer for repair/replacement.

CAUTION: Inaccurate gauge calibration may lead to a high suction condition applied to the patient.

5. With the control valve in the OFF position, suction should be at atmospheric and gauge should read zero. With suction port occluded, gauge should read zero.

6. With the control valve in the REG, set the Regulator to the middle of the scale and turn control valve to OFF, then back to REG or CONTIN. Gauge indicator should not travel more than 20% past the set point before settling at the desired level.
7. A final, important step in instrument maintenance is the identification of the instrument. This confirms that a qualified individual performed service to accepted procedures and approved master gauges. An ID tag should accompany the instrument, which indicates (as a minimum): date of service, individual performing the service and the date of next service.

CAUTION: Have the regulator factory serviced if not performing to specifications. See Warranty and Repair on p.16 for details on getting your instrument factory serviced.

Cleaning & Disinfection

Please refer to Boehringer document 7700.192, Boehringer Suction Regulator Recommendations for Decontamination and Autoclaving for guidance. This information is available online at www.boehringerlabs.com, or toll-free at 1-800-642-4945.

DISASSEMBLY

Refer to Figure 1 on page 15 for the appropriate diagram.

Regulator:

1. Back out lock screw (8) on housing assembly (7) with 1/16 hex wrench.
2. Unscrew diaphragm housing (7) from regulator body (12).
3. Remove valve retaining screw (9) and washer (10) with 5/32 hex wrench. Pull out control valve (15).
4. Check the cross passages on the control valve (15) to ensure it is clear of any obstruction.

IMPORTANT *The regulator body (12), control valve (15), and CASS valve assembly are factory mated. If servicing multiple regulators ensure these parts remain matched. Do not disassemble the CASS valve internals, If service is needed please contact the factory.*

5. In the unlikely event suctioned material should enter the regulator diaphragm housing, it will be necessary to disassemble and scrub the unit as follows:
 - a. Remove quad ring (5), lens cap retaining ring (1) and lens cap (2).
 - b. Push out diaphragm (3) by pressing on piston/stem assembly (4).
 - c. Remove piston/stem assembly (4) and spring (6).

Gauge:

6. Remove the retaining ring (17) using retaining ring pliers. From the front of the gauge, use thumb to rotate and loosen view tube (19). Then remove view tube-piston-diaphragm assembly (19-20-21).
7. Remove the lower lip of the diaphragm from outside of the view tube, and slide out the diaphragm-piston assembly.
8. Remove the upper diaphragm lip from the top of piston, and slide diaphragm off piston.
9. Remove spring (22).

NOTE *It is not necessary to remove the gauge body (24) from the regulator body (12) prior to cleaning.*

IMPORTANT *Always clean the unit prior to assembly. See Cleaning and Disinfection pg 10 for details.*

ASSEMBLY

After disassembling and cleaning the instrument, assemble and lubricate as follows. Parts are available from Boehringer Laboratories and may be ordered by part number (P/N). Part numbers are found in figure 1 at the end of this manual.

1. Lubricate control valve (15) and CASS valve assembly over entire mating surface with synthetic lubricant (P/N 1895).
2. Rotate both valves and inspect for dry areas before they are reassembled. The valves must have a thin layer of lubricant over their entire diameter without excess in the cross ports.
3. Lubricate the threaded sleeve in diaphragm housing (7) and U-cup (11) with a light coat of synthetic lubricant (P/N 1895).
4. Assemble diaphragm housing in reverse order of disassembly.

NOTE *The CASS valve must depress easily and return to its original position upon reassembly.*

5. Inspect quad ring seal (5) for cuts or wear. Replace if needed.
6. Assemble unit in reverse order of disassembly.

Gauge:

7. Slide large end of diaphragm (20) over piston (21) until top ring snaps into groove in piston. Be certain the top bead of the diaphragm is completely engaged into the groove of the piston.

CAUTION *If the diaphragm is not seated properly it will rub against the view tube and may lead to premature failure of the gauge.*

8. Slide view tube over diaphragm-piston assembly.
9. Roll edge of diaphragm around bottom of view tube and into groove. Make sure there are no folds or twists and that diaphragm is smooth.
10. Insert spring (22) into piston/view tube subassembly.
11. Slide piston subassembly with spring up (gauge body facing down) into gauge body (24).
12. Press until view tube assembly rests on shoulder in gauge body.
13. Assemble retaining ring (17) into groove in gauge body.

Regulator:

14. Place spring (6) on piston/stem assembly (4) and then insert through diaphragm housing assembly (7).
15. Cover piston/stem assembly (4) with lens cover (2) and snap lens cap retaining ring (1) into groove.
16. Assemble quad ring (5) to stem (4), then screw housing into body (12).
17. Tighten lock screw (8) to retain diaphragm housing on regulator body groove.
18. Insert the control valve (15), and position the valve retaining washer (10) before securing it with the valve retaining screw (9)

IMPORTANT *Always clean the unit prior to assembly. See Cleaning and Disinfection pg 10 for details.*

TROUBLESHOOTING

Complete Technical Manuals and Service Bulletins can be found at
<http://www.boehringerlabs.com/support/suction-regulator-technical-manuals.php>

Video Tips and Techniques for use and repair can be found at:
<http://www.boehringerlabs.com/support/video/product-videos.php>
<http://www.youtube.com/boehringerlabsllc>

Boehringer Suction Regulators have been designed for years of trouble-free service. Should you experience difficulty that is not the result of damage to the instrument, the most likely cause is aspiration of dirt and/or fluids into the Regulator.

Symptom	Probable Cause	Solution
Instrument fails to provide suction at the patient port.	The supply or patient fittings are clogged	Replace or clean the fittings
Gauge doesn't respond to changes in suction (via control valve or adjustment knob)	Gauge diaphragm is improperly sealed on the gauge piston and/or view tube	Disassemble gauge and check the position of the gauge diaphragm.
Gauge piston is discolored	Material has entered the inside of the gauge	Instrument is contaminated. Disassemble and clean the instrument.
Gauge responds slowly to changes in suction	The small hole in the top of the View Tube may be plugged.	Using a small diameter probe, pierce the hole to clear the obstruction.
Instrument will not shut off or exhibits high droop	Dried fluids may have cut the quad ring seal.	Replace the quad ring (5) and Test the unit as per above procedure.
Instrument fails to regulate suction	Piston/Stem surface is binding with foreign matter	Disassemble and clean the instrument.
Erratic gauge movement resulting from regulator adjustment	Gauge is not sealed	Make sure retaining ring (17) is seated in groove on the gauge body and there is no end play in the view tube (19).

IMPORTANT Always test the reassembled unit after each maintenance procedure.

 See the Test section, page 9, for exact test procedure.

SPECIFICATIONS

- Inlet and outlet fittings: 1/8 NPT
- Gauge accuracy $\pm 5\%$ FS
- Regulation Accuracy: $\pm 10\%$ FS from full flow to zero flow with 14 FR catheter attached.
- Leak rate in OFF position: less than 1 cc/min
- Free Air Flow: Greater than 38 LPM with regulator set to 100 mmHg at standard JCAHO supply (305mmHg @ 180 SCFH) and a typical collection circuit.
- Materials: polycarbonate, hard-anodized aluminum, stainless steel, Buna rubber, silicone, acetal copolymer.

Model	Regulation Range	User Selectable Modes	Wt. (lb)*	H x W x D (in)
3720	6-60 mm Hg	Off, Regulated Control,	1.35	5 $\frac{1}{4}$ x 2 $\frac{1}{2}$ x 4

*Regulator weights are without fittings.

Operating and Storage Limits

We recommend that Boehringer Suction regulators be operated and stored at controlled conditions that typically reflect the medical facility environment.

ACCESSORIES

Integral Trap Bottle – Model 9100



Inline Filter – Model 7791

This device will protect your regulators and suction system from fluid overflow. It is a hydrophobic, high flow, 1.0 micron filter and can be EtO sterilized. The filter goes in the patient circuit between the waste canister and the regulator.



WARRANTY AND REPAIR

Boehringer Laboratories, Inc. guarantees all 3700 Series LONG LIFE Suction Regulators for TEN years. Boehringer Laboratories, Inc. will also warrant all fittings purchased from and installed by Boehringer Laboratories, Inc. for the same warranty period as the suction regulator on which they were originally installed.

Boehringer Laboratories, LLC warrants to the original purchaser, new suction regulators purchased directly from Boehringer Laboratories, LLC or from an authorized dealer or representative. This warranty guarantees the suction regulators to be free from functional defects in materials and workmanship. We also guarantee that our suction regulators will meet our published specifications.

All regulators returned for repair shall be clean and free from contamination prior to shipment to Boehringer Laboratories. This requirement is for the safety of our employees as well as to comply with Federal Law prohibiting the shipment of unmarked biohazard materials. If units are returned contaminated, a cleaning charge may result.

A service charge may be assessed on any unit returned that shows evidence of gross abuse.

Boehringer Laboratories, LLC is the only authorized warranty service center for our suction regulators. Any repair service requesting a return authorization for repair will be asked to provide the name and location of the original equipment purchaser. If this information cannot be provided, the repair is not covered under warranty and will be a chargeable repair.

This warranty excludes acts of God, fire, flood and acts of war, terror or insurrection.

This warranty is not transferable from the original purchaser.

Boehringer Laboratories' sole and exclusive remedy under this warranty is limited to repairing and/or replacing the suction regulator. There are no other express or implied warranties beyond these warranties set forth above. At Boehringer Laboratories, we are committed to lowering your suction regulator costs of operation!



All repairs will be shipped back within five days of receipt of purchase order authorization.

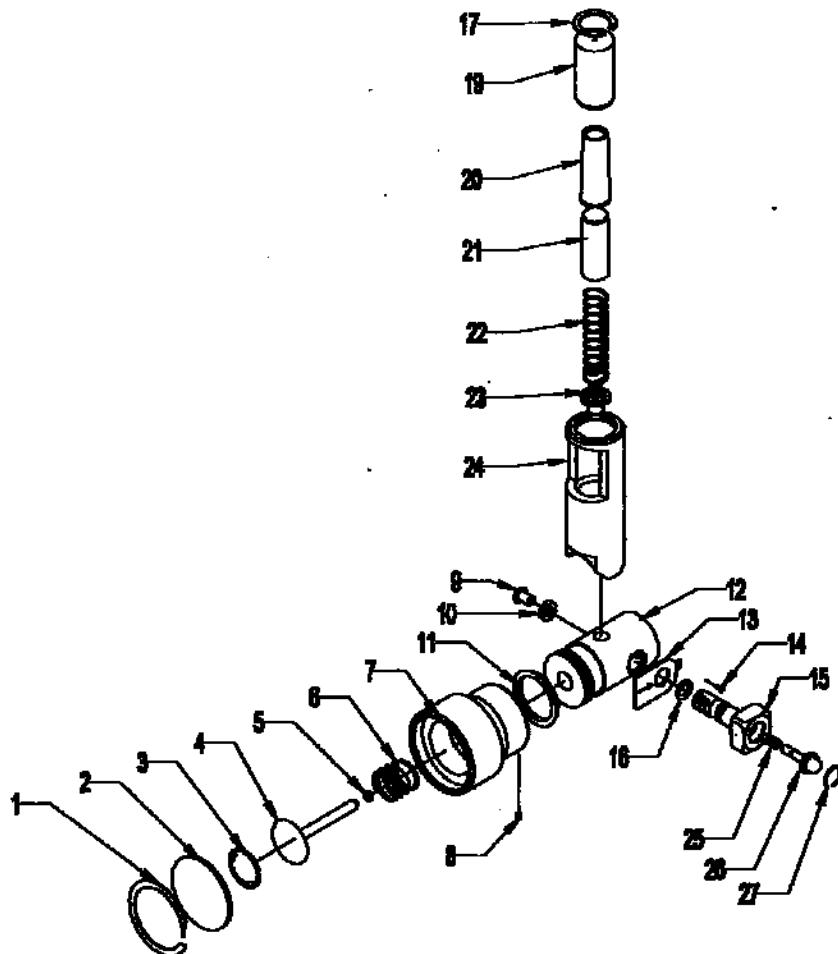
For quality factory service, call 800-642-4945 or 610-278-0900 for your return authorization. Ship returns to:

**Boehringer Laboratories, LLC
Repair Department
300 Thoms Dr.
Phoenixville, PA 19460**

New Products

We are continually striving to reach higher and higher standards of quality. We value your comments and input on our suction regulators. If you are pleased with this instrument, please find out more about Boehringer Laboratories' complete line of suction controls.

FIGURE 1
Model 3720 (pictured)



<u>No.</u>	<u>P/N</u>	<u>Description</u>	<u>No.</u>	<u>P/N</u>	<u>Description</u>
1	1465BF	Lens Cap Retaining Ring	14	1480	Thumb Spring Retaining Screw
2	33568	Lens Cap, Model 3720	15	***	Control Valve
3	1466	Regulating Diaphragm	16	353	Control Valve O-Ring
4	2297	Piston/Stem Assembly	17	33038	Gauge Retaining Ring
5	1461	Quad Ring	19	33040	Gauge View Tube
6	1464	Spring, 200 mm Hg	20	33042	Gauge Diaphragm
7	1871	Diaphragm Housing Ass'ly	21	33036HS	Gauge Piston
8	33582	Lock Screw	22	33563	Gauge Spring, 60 mm Hg
9	1468	Control Valve Retaining Screw	23	33043	Fastener
10	1454	Control Valve Retaining Washer	24	33571AN	Gauge Body with Label, 60 mm Hg
11	1484	U-cup	25	***	CASS Valve Spring
12	***	Reg Body	26	***	CASS Button Assy
13	1462	Thumb Spring	27	***	CASS Valve Retainer

***. The Reg Body, Control Valve, and CASS Button Assy. are factory matched and will be factory serviced only.



Boehringer Laboratories, LLC.
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Phoenixville, PA 19460

For
Customer Service
Or
Technical Support

800-642-4945
www.boehringerlabs.com

*A free trial evaluation
of any of our suction regulators
can be arranged by calling
(800) 642-4945 or 610-278-0900.*